Deutsche Bank
Research

Rating
Hold

North America
United States

Health Care
Medical Supplies & Devices

Company
Intuitive Surgical

Reuters	Bloomberg	Exchange	Ticker
ISRG.OQ	ISRG US	NMS	ISRG

Date
20 February 2020

Company Update

Price at 19 Feb 2020 (USD)	614.88
Price Target	595.00
52-week range	615.00 - 458.27

Deeper Dive on Third Party Risk to I&A Segment

Valuation & Risks

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Our February 3rd downgrade was predicated on our belief that refurbished da Vinci instruments pose a material (and increasing) risk to Intuitive's I&A segment growth over the next couple years. Not surprisingly, pushback has centered largely around two points:

1. the presumed regulatory barriers and the view that third-parties engaged in instrument repair are in violation of FDA regulations;
2. hospitals engaging with these third parties are doing so in violation of their customer supply/service contracts with Intuitive.

Deeper dive into the threat from refurbished da Vinci instruments. Over the past few weeks, we consulted with five regulatory and legal experts to gain further clarity on both the regulatory/FDA and service contract angles.

- On the FDA side, while some acknowledged that applicable regulations are somewhat nebulous, a majority of regulatory experts came to the conclusion that Restore Robotics is not in violation of FDA rules as a third-party service provider of refurbished instruments.
- Conversations with both health systems and surgeons since our downgrade have yielded further confirmation that utilization of refurbished robotic instruments is starting to gain traction.
- Intuitive customers also provided additional insights into ISRG's stance and pushback strategy – and importantly, also how hospitals are responding to Intuitive's advisement to cease and desist engagement with service providers.
- Notably, some hospitals are now beginning to push back on restrictions embedded in their service contracts against third party servicing of da Vinci systems and instruments, questioning the legality and enforceability of such terms of service.

We believe the Street continues to be overly dismissive of the risk of increasing usage of refurbished da Vinci instruments to Intuitive's top line over the next couple years. Given the abundance of first-hand confirmation from hospital customers that are exploring refurbished instruments, the question is not whether – but rather, how much – Intuitive's business will be impacted.

Even with modest unit share capture, revenue hit would be meaningful. We continue to believe 4-6% penetration of Intuitive's *de novo* instruments on a unit basis in 2021 is reasonable and, based on our additional diligence, potentially conservative. And even with this modest unit share capture, the resultant impact to Intuitive's top-line would be amplified given that each instrument can be repaired multiple times. In our base case scenario of 5% *de novo* unit share capture in 2021 and the assumption that each instrument is repaired 3x on average, our analysis indicates a top-line hit on the order of $193 million or 3.4% of total company sales in 2021.

Bottom line: barriers to entry may not be as strong as presumed

FDA experts concur that FDA action to stymie usage of repaired instruments is highly unlikely.

- Contrary to the viewpoint that third parties require 510(k), our takeaway from these consultants is that 510(k) clearance does not seem to be required for independent service organizations refurbishing used da Vinci instruments so long as they are returned to that same hospital and not re-sold to other centers.
- Regardless, all experts agreed that any regulatory action/enforcement is highly unlikely given FDA's clear comfort around the safety of refurbished devices broadly and the fact that there has been no signal of incremental patient risk to date with repaired da Vinci instruments.
- In fact, Intuitive acknowledged in a recent cease and desist notice to a hospital customer that "FDA has indicated that it will exercise a certain degree of enforcement discretion from FDA quality system requirements as they apply to third party service providers and refurbishers."

Contractual terms of agreement may not be an airtight impediment to hospital adoption.

- As has always been the case, Intuitive's hospital customer contracts include stipulations prohibiting engagement with third parties for servicing of both da Vinci systems and instruments/accessories, and that violation of these clauses could render supply/service contracts null and void
- **However, our work indicates that some hospitals are beginning to push back on these contractual limitations and questioning their legal voracity and enforceability. We have heard firsthand from customers, including large hospital systems, planning to (or considering) pursue legal action against Intuitive within the next 12 months.**

Net-net. We have a high level of evidence-based conviction that repaired da Vinci instruments are beginning to gain traction among hospitals, with usage likely to continue to expand over the next couple years. We note two potentially meaningful near-term stimulants of increased adoption:

(1) significantly greater commercial distribution (Medline, a major distributor with substantial sales/marketing/distribution footprint, recently became a distributor for Restore Robotics)

(2) expansion of offerings to include repaired X/Xi instruments expected near-term.

Why printer cartridges could be highly relevant

We highlight later in this note the specific terms of agreement enumerated in Inituitive's customer contracts that hospitals are now starting to question, largely on the basis of a precedent legal case - IMPRESSION PRODUCTS, INC. v. LEXMARK INTERNATIONAL, INC. – that legal consultants think could ultimately have huge implications for Intuitive's entire business model

The US Supreme Court issued a ruling on this remarkably analogous case in 2017, with Justice Roberts writing:

"We conclude that a patentee's decision to sell a product exhausts all of its patent rights in that item, regardless of any restrictions the patentee purports to impose or the location of the sale. In sum, patent exhaustion is uniform and automatic. Once a patentee decides to sell—whether on its own or through a licensee—that sale exhausts its patent rights, regardless of any post-sale restrictions the patentee purports to impose, either directly or through a license.

Some hospitals we spoke with believe Intuitive's contract terms could be in violation of this USSC ruling in the Lexmark case, thus rendering them invalid and unenforceable.

Litigation acknowledged as risk factor in latest 10K filing. Regarding the antitrust lawsuit filed by Restore Robotics in February 2019 (and countersuit subsequently filed by Intuitive), Intuitive has now acknowledged the litigation as a shareholder risk factor in its 10K filed two weeks ago.

Source: PACER.gov, company filings, Deutsche Bank

Clarity Around Key Regulatory Considerations

Insights from four regulatory consultants with experience and expertise specifically in the arena of third party servicing medical devices:

- Former staffer within the CDRH division of FDA;
- Regulatory expert who has worked with various medtech companies in managing hundreds of 510(k) and PMA submissions over decades of industry experience;
- Two regulatory affairs personnel at large medtech companies with significant presence in device refurbishing/reprocessing.

These consultations provided a lot more clarity around a number of critical points determining the regulatory parameters these serviced instruments are subject to, such as

- Distinction between servicing and marketing of limited-use devices by third parties like Restore Robotics versus single use devices;
- Refurbishing versus remanufacturing and the significant differences in regulatory oversight of one versus the other;
- Sterilization processes, which is closely scrutinized by FDA;
- Regulatory oversight of third party facilities where used instruments are serviced.

Our takeaway from speaking with these consultants is that 510(k) clearance clearly is not be required for independent service organizations (ISOs) such as Restore Robotics in repairing used limited-use da Vinci instruments for hospitals and returning them to the hospital for continued usage.

Servicing versus Remanufacturing: a key distinction

The critical distinction is the categorization of used instruments serviced by third parties for additional use given the significant implications vis-à-vis regulatory oversight. The FDA defines "service" and "remanufacture" as follows:

- **Service:** "Repair and/or preventative or routine maintenance of one or more parts in a finished device, after distribution, for purposes of returning it to the safety and performance specifications established by the OEM and to meet its original intended use. Servicing excludes activities that change the intended use of the device from its original purpose, or change the safety or performance specifications. However, it is important to note that FDA considers remanufacturing to be a distinct activity from servicing that raises different concerns, and is thus regulated differently. FDA considers servicing to include refurbishing, reconditioning, rebuilding, repairing, and remarketing, but not remanufacturing."

- **Remanufacture:** Process, condition, renovate, repackage, restore, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.

We believe da Vinci instruments currently refurbished by Restore Robotics clearly fall under the definition of "service" as the process these used instruments undergo are intended to return them to "the safety and performance specifications established by the OEM and to meet its original intended use" and do not involve "activities that change the intended use."

Importantly, the serviced instruments are always shipped back to the original hospital (i.e. no reselling) and the instruments are shipped back to the hospital only after verification that there has been no deviation from the original "performance or safety specifications."

Simply put, surgical scissors have been serviced by ISOs for decades. So why should scissors affixed to a robotic arm be structurally different? It is important to keep in mind that repaired instruments are limited to relatively simple devices like scissors and graspers and not advanced instruments like staplers.

Source: FDA.gov

Servicing versus Remanufacturing: a key distinction

FDA consultant underscored that ownership is a key determinant of regulatory requirements and FDA oversight broadly.

- When a hospital purchases an instrument from Intuitive, the hospital takes ownership of the device
- So when the hospital sends the instrument to a third party like Restore Robotics for refurbishment, the third party is acting as a contractor providing a service for the hospital
- That is, ownership of the device never actually changes hands.

Another FDA expert we consulted fully concurred, noting that once an instrument is purchased it becomes property of the hospital which is free to "do whatever it wants with it."

- The consultants did however point out that the instrument's warranty from the manufacturer would expire after the 10x uses and the hospital/third party would thereby assume liability.
- In speaking with Restore and Medline, neither disagreed with this point and pointed out that standard insurance policies are in place in acknowledgement of this assumed liability. Medline pointed out that the cost to warranty these type of instruments is fairly immaterial

All of our consultants emphasized that a used instrument that is sent to a third party for repair must be shipped back only to that same hospital such that there is no change in ownership. We confirmed with both hospitals and Restore that such is indeed the case here.

510(k) Premarket Notification does not appear applicable

The immediate feedback to our downgrade note was that Restore Robotics is subject to 510(k) approval requirement and that because the company does not have 510(k) clearance it is therefore in clear violation of FDA regulations.

However, most of our regulatory experts we spoke to suggested that this argument is fundamentally misplaced.

One consultant noted that the non-applicability of 510(k) approval is made quite clear by simply considering the FDA's official definition of this process:

510(k) Premarket Notification

FDA Home ◉ Medical Devices ◉ Databases

A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR §807.92(a)(3)) that is not subject to premarket approval.

The agency's definition explicitly qualifies application of 510(k) standards to devices intended to be marketed.

Because third parties are providing a service to the hospital and not commercially marketing the repaired instruments, by definition this precludes the obligation of having 510(k) clearance.

Source: FDA.gov

Sterilization processes are highly regulated by FDA

FDA expert pushback

- One consultant believed Restore Robotics would need to have 510(k) clearance because these limited use instruments are required to undergo a cleaning and sterilization process prior to initial use and between all subsequent uses, per the 510(k) clearance from the FDA.

- Because sterilization processes are highly scrutinized by the FDA due to potential public safety risk, she raised the possibility that 510(k) might thus be necessary.

- For example, all single use refurbished equipment that is sterilized REQUIRE 510k approval

- However, post that expert call, we confirmed that the instrument repair process actually does NOT involve sterilization – thus rendering this point moot.

- When the repaired instrument is returned to the hospital, it remains subject to exactly the same cleaning/sterilization requirements outlined in the IFU.

In other words, there is no disruption to the IFU approved by the FDA as part of the 510(k) clearance vis-à-vis sterilization protocol from the repair of da Vinci instruments.

Source: FDA.gov, Deutsche Bank

Regulatory oversight of facilities: ISO certification is the standard

Companies engaged in servicing of devices for the hospital operate under ISO certification, which are obtained from third parties that inspect all facets of the facility where these repairs happen. This inspection includes quality control to confirm that the repair process restores the device to specifications in line with product labeling and with no changes to intended use or safety profile. As noted earlier, FDA makes a clear distinction between remanufactured versus serviced devices in terms of regulatory oversight including facilities.

Facilities where third parties service and refurbish instruments are not subject to FDA oversight. Essentially, these facilities need to operate to the satisfaction of hospitals, and having ISO certification is largely what the vetting process of hospitals centers around.

We were able to review a third party ISO certification received by Restore Robotics for the servicing of endowrist instruments. We confirmed that the issuer of this certification, a Germany-based company called DQS MED, is reputable and credible in the medtech industry – e.g., just a few months ago, this same organization granted ISO certification to a Medtronic facility.

Net-net: (1) FDA consultants agree that 510k clearance clearly appears to be not applicable, (2) regardless, given the lack of any signal of incremental patient risk with repaired instruments, any FDA enforcement action to curtail usage is highly unlikely unless the restored equipment causes patient harm.

Specifically, Restore has been engaged in refurbishing Intuitives' products for over 18 months. Its safe to believe that Intuitive has brought this to FDA's attention. Per our consultants, if the FDA doesn't act on this information within 3-6 months, it is unlikely the FDA ever will.

Source: FDA.gov, Deutsche Bank estimates

FDA's general comfort around refurbished devices is quite clear…and Intuitive agrees that enforcement activity by FDA is unlikely

- Third-party servicing of medical devices has been widespread across the industry for many years, including large segments like endoscopes and laparoscopic devices;

- Third parties engaged in this practice are closely regulated and, per figures cited by the FDA, there are close to 20K companies just in the US that are in the business of servicing used medical devices;

- **FDA's stance on third-party servicing of medical devices is clear.** In May 2018, the agency published its views in its report, *FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices*

  The document states that there insufficient basis to "justify imposing additional/different, burdensome regulatory requirements at this time; rather, the objective evidence indicates that many OEMs and third-party entities provide high quality, safe, and effective servicing of medical devices."

  Net/net, FDA posits that "The continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system."

Intuitive acknowledges that regulatory enforcement actions of third party service providers broadly are unlikely, noting in a written correspondence to a hospital customer that FDA will likely "exercise a certain degree of enforcement discretion from FDA quality system requirements as they apply to third party service providers and refurbishers."

Source: FDA.gov, Deutsche Bank estimates

Additional insights into Intuitive's stance and points of pushback

In cease-and-desist letters sent to hospitals that have begun (or could soon begin) using refurbished da Vinci instruments, Intuitive justifies its stance on safety, regulatory, and legal/contractual grounds.

- **Safety**
  - Some of the specific points made by the company regarding risks around servicing of limited-use robot consumables do not seem to be relevant.
  - For example, one area of emphasis for Intuitive is sterilization and the significant safety risks deviations from sterilization protocols that were okayed by FDA as part of 510(k) device approval.
  - However, the repair processes that these instruments undergo do not actually involve sterilization, and the sterilization process these devices are required to undergo between uses remains exactly the same once the instrument is refurbished.
  - In other words, the repaired instrument is sent back must undergo the same pre-operative steps as a de novo instrument shipped from Intuitive prior to the initial use.

- **Regulatory considerations.**
  - Intuitive cautions customers that third party repairs of da Vinci instruments are in violation of FDA regulations and specific IFUs included in each device's 510(k) approval.
  - However, our work suggests that there is likely no actual violation of regulatory guidelines by third parties in refurbishing the devices nor by the hospital in utilizing them.

- **Legal / Contractual grounds**
  - Customer contracts explicitly prohibit third party servicing of instruments/robots and that violations could render the contract null and void. Hospitals are now beginning to question Intuitive's ability to enforce this.

Hospitals starting to pushback on legality/enforceability of terms of service

In no uncertain terms, the standard terms of service outlined in customer contracts state that hospitals are precluded from engaging with third parties as well as the potential consequences of violation – nullification of contracts, product warranties, etc.

- *Instruments and Accessories are subject to a limited license to use those Instruments and Accessories with, and prepare those Instruments and Accessories for use with, the System. Any other use is prohibited, whether before or after the Instrument or Accessory's license expiration, including repair, refurbishment, or reconditioning not approved by Intuitive, and cleaning and sterilization inconsistent with Documentation. This license expires once an Instrument or Accessory is used up to its maximum number of uses specified in the Documentation accompanying the Instrument or Accessory.*

- *Customer agreed that it will not, nor will Customer permit any third party to, modify, disassemble, reverse engineer, alter, or misuse the System or Instruments and Accessories. Customer further agreed that if Customer fails to comply with the requirements listed above, Intuitive may terminate the Agreement immediately upon written notice, and any warranties applicable to the System will become void.*

Source: Intuitive Surgical, industry contacts

Hospitals starting to pushback on legality/enforceability of terms of service

What has changed? While restrictions around third party servicing of da Vinci instruments and robots have always been a standard part of customer contracts, we have learned that hospitals are now starting to push back on these clauses.

1. Usage of repaired instruments was simply not an option previously. Hence, there was no pushback from hospitals – but with this option now available from third parties like Restore Robotics, we are starting to see hospitals question the actual legality of these terms.

2. Recent Supreme Court ruling in the IMPRESSION PRODUCTS, INC. v. LEXMARK INTERNATIONAL, INC. case. As highlighted below, the aforementioned terms of agreement stipulated in Intuitive's service contracts could potentially be in conflict with the SCOTUS opinions articulated in this decision.

SCOTUS docket No 15-1189: Why printer cartridges could be highly relevant

SUPREME COURT OF THE UNITED STATES

Syllabus

IMPRESSION PRODUCTS, INC. *v.* LEXMARK INTERNATIONAL, INC.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 15–1189. Argued March 21, 2017—Decided May 30, 2017

This landmark case is highly analogous to the customer restrictions stipulated in the terms of service of Intuitive's customer contracts.

When Lexmark sells toner cartridges, it gives consumers two options: One option is to buy a toner cartridge at full price, with no restrictions. The other option is to buy a cartridge at a discount through Lexmark's "Return Program." In exchange for the lower price, customers who buy through the Return Program must sign a contract agreeing to use the cartridge only once and to refrain from transferring the cartridge to anyone but Lexmark.

Companies known as remanufacturers acquire empty Lexmark toner cartridges—including Return Program cartridges—from purchasers in the United States, refill them with toner, and then resell them. They do the same with Lexmark cartridges that they acquire from purchasers overseas and import into the United States. Lexmark sued a number of these remanufacturers, including petitioner Impression Products, Inc., for patent infringement with respect to two groups of cartridges.

Source: PACER.gov, Deutsche Bank estimates

SCOTUS docket No 15-1189: Why printer cartridges could be highly relevant

The US Supreme Court found the stipulations imposed by Lexmark on its customers restricting what these customers do with printer cartridges they have purchased to be unlawful

- *When a patentee sells one of its products, the patentee can no longer control that item through the patent laws—its patent rights are said to "exhaust."*
- *The purchaser and all subsequent owners are free to use or resell the product just like any other item of personal property, without fear of an infringement lawsuit.*

This case presents two questions about the scope of the patent exhaustion doctrine:

- *First, whether a patentee that sells an item under an express restriction on the purchaser's right to reuse or resell the product may enforce that restriction through an infringement lawsuit.*
- *Second, whether a patentee exhausts its patent rights by selling its product outside the United States, where American patent laws do not apply.* ***We conclude that a patentee's decision to sell a product exhausts all of its patent rights in that item, regardless of any restrictions the patentee purports to impose or the location of the sale.***

In sum, patent exhaustion is uniform and automatic. ***Once a patentee decides to sell—whether on its own or through a licensee—that sale exhausts its patent rights, regardless of any post-sale restrictions the patentee purports to impose, either directly or through a license.***

Source: PACER.gov, Deutsche Bank estimates

Quantifying the Risk to US I&A Revenues

To quantify Intuitive's revenues at risk from inroads by third-party instrument repairs, we queried the DB US Medtech Database which provided us with a meaningful sample size: 8.2% of 2019 reported US I&A segment revenues.

We looked at 2019 revenues for all instrument SKUs currently eligible for third-party repair – which, as noted, are currently limited to the da Vinci S/Si product portfolio.

SKU	Description	% of I&A revenue	SKU	Description	% of I&A revenue
420179	SCISSORS MONOPOLAR STERILE DISPOSABLE 38- D CURVE L55.9 CM L1.3 CM OD8 MM	6.71%	420001	SCISSORS LAPAROSCOPIC POTTS 22- D L54.5 CM L1.1 CM	0.04%
420006	DRIVER NEEDLE ENDOWRIST DA VINCI S/SI 30- D LARGE L54.4 CM L1 CM OD8 MM	3.12%	420048	FORCEPS DA VINCI S/SI LONG OD8 MM STERILE	0.04%
420205	FORCEPS BIPOLAR LAPAROSCOPIC ENDOWRIST S/SI 45- D MEDIUM L55.9 CM L2.1 CM OD8 MM	2.98%	420278	RETRACTOR LAPAROSCOPIC GRAPTOR 60- D L56.7 CM L5.4 CM OD8 MM	0.04%
420093	FORCEPS LAPAROSCOPIC PROGRASP S/SI 38- D L56.2 CM L2.8 CM OD8 MM GRASPER	2.21%	420033	FORCEPS LAPAROSCOPIC DA VINCI S/SI ENDOWRIST 30- D MICRO DIAMOND L54.4 CM L1 CM OD8 MM	0.03%
420309	DRIVER NEEDLE SUTURECUT ROBOTIC 23- D MEGA L49.7 CM L1.4 CM OD8 MM	1.97%	420007	SCISSORS LAPAROSCOPIC DA VINCI S/SI ROUND L54.5 CM L1.1 CM OD8 MM	0.02%
420172	FORCEPS MARYLAND BIPOLAR 2 CMX8 MM MED	1.41%	420178	SCISSORS LAPAROSCOPIC CURVE STERILE DISPOSABLE L54.7 CM L1.3 CM OD8 MM MEDIUM	0.02%
420227	BIPOLAR FORCEPS LAPAROSCOPIC S/SI ENDOWRIST PK 70- D L55.4 CM L2 CM OD8 MM	1.32%	420249	RETRACTOR LAPAROSCOPIC 2 BLADE	0.01%
420194	DRIVER NEEDLE MEGA 30-DX54.7CMX1.3CM	1.27%	420181	FORCEPS GRASPING DISPOSABLE RESANO 30- D MEDIUM L54.5 CM L1.1 CM OD8 MM	0.01%
420049	FORCEPS LAPAROSCOPIC 38 D L32.77 CM L2 CM OD8 MM	0.69%	420246	RETRACTOR LAPAROSCOPICT RIGHT CURVE OD8 MM	0.01%
420183	HOOK DA VINCI S/SI L55.2 CM L1.6 CM OD8 MM	0.36%	420036	FORCEPS LAPAROSCOPIC DAVINCI 30-D MEDIUM L54.6 CM L1.2 CM OD8 MM	0.01%
420296	DRIVER NEEDLE SUTURECUT 30- D 54.5 CM X1.1 CMX8 MM LRG	0.28%	420157	BLADE ENDOSCOPIC 8 MM L54.6 CM L1.2 CM OD8 MM	0.01%
420190	GRASPER ENDOSCOPIC DA VINCI S 60- D COBRA L55.4 CM L2 CM OD8 MM LOW FORCE	0.22%	420171	FORCEPS LAPAROSCOPIC 45- D MICRO L55.2 CM L1.4 CM STERILE	0.01%
420207	FORCEPS LAPAROSCOPIC TENACULUM 75- D L56.4 CM L3 CM OD8 MM	0.16%	420215	FORCEPS GRASPER CARDIAC PROBE DAVINCI S/S OD8 MM	0.00%
420184	ELECTRODE CAUTERY SPATULA MONOPOLAR STERILE DISPOSABLE L1.7 CM OD8 MM	0.11%	420121	FORCEPS FINE TISSUE 54.5 CMX8 MM	0.00%
420189	GRASPER LAPAROSCOPIC DA VINCI S/SI ENDOWRIST L56.7 CM OD8 MM	0.08%	420110	FORCEPS LAPAROSCOPIC PRECISE BIPOLAR OD8 MM	0.00%
420318	RETRACTOR ENDOSCOPIC ENDOWRIST DA VINCI S/SI GRAPTOR SMALL GRASP	0.07%	420192	Valve Hook	0.00%
420003	APPLIER CLIP SMALL HEMOCLIP TITANIUM 8 MM	0.05%	420203	Pericardial Dissector	0.00%
420344	DISSECTOR BIPOLAR CURVE CAUTERY 8 MM	0.04%	420204	Atrial Retractor	0.00%

In total, we estimate that ~23% of Intuitive's US I&A segment revenues are exposed to potential impact from third-party repair.

- This represents a big decline versus 2018, when these consumable devices accounted to about 35% of segment sales mix, reflecting the continued mix shift toward X/Xi products.

Source: Global Healthcare Exchange LLC, Deutsche Bank estimates

Quantifying the Risk to US I&A Revenues

It is our understanding that da Vinci instrument repairs are expected to become available for instruments in the X/Xi product suite around mid-2020 – which is significant given the continued mix shift toward the latest-generation instruments and away from the S/Si catalog.

And while it is not yet clear specifically which X/Xi instrument SKUs will be available for third-party repair, our analysis assumes that these will include the corresponding iteration of those currently being serviced within the prior-generation S/Si family.

SKU	Description	% of I&A revenue	SKU	Description	% of I&A revenue
470179	SCISSORS MONOPOLAR HOT SHEARS ENDOWRIST 38 D CURVE L31.75 CM L1.3 CM OD8 MM	14.01%	470033	FORCEPS LAPAROSCOPIC L1 CM L31.5 CM	0.06%
470006	DRIVER NEEDLE ENDOWRIST 30 D LARGE L31.5 CM L1 CM OD8 MM	4.97%	470249	RETRACTOR LAPAROSCOPIC 70 D L33.27 CM L4.8 CM OD8 MM 2	0.06%
470309	DRIVER NEEDLE MEGA SUTURE CUT 0-35 D L1.4 CM	4.82%	470246	RETRACTOR LAPAROSCOPIC 60 D SHORT L33.27 CM L4.8 CM OD8 MM	0.04%
470172	FORCEPS LAPAROSCOPIC MARYLAND 45 D L32.77 CM L2 CM OD8 MM	2.97%	470171	FORCEPS BIPOLAR MICRO	0.04%
470049	FORCEPS LAPAROSCOPIC CADIERE DA VINCI XI 38 D L32.77 CM L2 CM OD8 MM	2.81%	470215	GRASPER DA VINCI XI 60 D L32.26 CM L1.7 CM OD8 MM	0.03%
470194	DRIVER NEEDLE 38 D L31.75 CM L1.3 CM OD8 MM	1.79%	470181	FORCEPS ENDOWRIST L31.75 CM L1.1 CM OD8 MM	0.02%
470296	DRIVER NEEDLE SUTURECUT 38 D 31.50 CMX1.1 CMX8 MM LRG	1.28%	470190	GRASPER LAPAROSCOPIC COBRA 68 D L32.51 CM L2 CM	0.00%
470318	RETRACTOR LAPAROSCOPIC 0-65 D SMALL L4.5 CM	0.76%	470036	FORCEP ROBOTIC XI DEBAKEY	0.00%
470205	FORCEPS BIPOLAR LAPAROSCOPIC 45 D L32.77 CM L2.1 CM	0.42%	470093	FORCEP ROBOT DAVINCI XI PROGRASP	0.00%
470344	DISSECTOR LAPAROSCOPIC 45 D	0.41%	470183	ROBOT DAVINCI XI PERMANENT MONOPOLAR CAUTERY HOOK	0.00%
470001	SCISSORS POTTS LAPAROSCOPIC 22 D L31.5 CM L1.1 CM OD8 MM	0.15%	470184-T	PERMANENT CAUTERY SPATULA	0.00%
470007	SCISSORS ROUND TIP 38 D L31.5 CM L1.1 CM	0.14%	470207	FCP TENACULUM XI	0.00%
470048	FORCEPS LAPAROSCOPIC 30 D L32.51 CM L2 CM	0.11%			

We estimate that the above X/Xi instruments collectively accounted for ~35% of 2019 US I&A segment revenues. As such, once third-party repairs of them become available, Intuitive's top line exposure will increase dramatically – rendering a majority (~58%) of segment sales "at risk" of competitive pressures.

	2018	2019
S/Si instruments	35%	23%
X/Si instruments	29%	35%
Total	64%	58%

Source: Global Healthcare Exchange LLC, Deutsche Bank estimates

Model Ramifications: Revenue & EPS Sensitivity

Our analysis of expected financial impact of third-party instrument repair encroachment presumes 58% of US I&A segment sales are addressable in 2021, per SKU-level analysis.

Based on 2021 consensus US I&A segment revenues of $2.224 billion, this would put $1.290 billion of Intuitive's sales at risk from increased utilization of repaired instruments. This equates to 23% of total company sales.

Based on our conversations with surgeon and hospital customers, we believe 4-6% penetration of Intuitive's *de novo* instruments on a unit basis in 2021 is reasonable and potentially even conservative. And even with this modest unit share capture, the resultant impact to Intuitive's top-line would be amplified given that each instrument can be repaired multiple times.

As such, our base case scenario of 5% *de novo* unit share capture in 2021 and the assumption that each instrument is repaired 3x on average, our analysis indicates a top-line hit on the order of $193 million or 3.4% of total company sales in 2021.

The model impact of this manifests on the US revenue per procedure line of our sales build, with zero impact to procedure volume growth.

2021E Consensus ($MM)	
Total company sales	$5,71
US Instruments & Accessories sales	$2,22
% of US I&A segment revenues at risk	58%
$ at risk	$1,29
% of total company revenues at risk	23%

% capture of addressable revs	Top line impact			EPS impact	
	$MM	% of US I&A sales	% of total sales	$	%
2.5%	$32	1.5%	0.6%	$0.09	0.6%
5.0%	$64	2.9%	1.1%	$0.18	1.1%
7.5%	$97	4.4%	1.7%	$0.27	1.7%
10.0%	$129	5.8%	2.3%	$0.35	2.2%
12.5%	$161	7.3%	2.8%	$0.44	2.8%
15.0%	**$193**	**8.7%**	**3.4%**	**$0.53**	**3.4%**
17.5%	$226	10.2%	4.0%	$0.62	3.9%
20.0%	$258	11.6%	4.5%	$0.71	4.5%
22.5%	$290	13.1%	5.1%	$0.80	5.0%
25.0%	$322	14.5%	5.6%	$0.88	5.6%
27.5%	$355	16.0%	6.2%	$0.97	6.2%

Source: Bloomberg Finance LC, Deutsche Bank estimates

Mitigants to Third-Party Encroachment

Intuitive expects that these matters will ultimately be resolved in the courts, and barring any unforeseen developments (i.e., settlement) the ongoing litigation with Restore Robotics will surely take several years to play out. However, in the meanwhile we do note multiple fundamental mitigating factors that will to some extent continue to blunt the impact.

- **Innovation.** Intuitive's R&D investments remain substantial ($430mm in 2019) with innovation now an even bigger core focus ahead of upcoming competitor system launches. Launch of new da Vinci platforms and advanced instruments will continue to yield a lower mix of I&A revenues vulnerable to third-party encroachment.

- **Usage based placements.** An increasing number of hospitals are acquiring new da Vinci systems via usage-based and operating lease arrangements, with systems like Mount Sinai beholden to instrument pricing based on volume thresholds and therefore disincentivized to utilize refurbished instruments.

- **Leveraging its dominant market position.** While some hospitals are now starting to question the legality/enforceability of contract terms of service, there are also those whose surgeons are simply unwilling to risk losing access to Intuitive's technologies. We spoke with a supply chain executive of a major academic center that recently began using repaired da Vinci instruments, but upon receipt of an ensuing cease-and-desist notice from the company's lawyers, stopped.

Litigation: Restore Robotics v. Intuitive Surgical

Developments in ongoing litigation will ultimately have significant implications, though resolution likely years away.

- In February 2019, Restore Robotics filed an antitrust lawsuit against Intuitive in the US District Court in the Northern District of Florida.

- Intuitive subsequently filed a countersuit against Restore Robotics comprising six counts that include unlawful business practices and fraud.

The case is currently in discovery phase and a jury trial is scheduled to commence in 2022, which barring settlement and potential for either side to appeal the jury's verdict indicates that resolution is likely several years away. And while we are not lawyers and thus not qualified to opine on the voracity of either party's claims in the lawsuit/countersuit nor handicap the potential outcomes, and despite the fact that final resolution is likely years away, we think investors should be cognizant of the case and developments over the next few years.

We do note that if hospital systems wanted to pursue legal action of their own against Intuitive, it would be via a separate filling in the state the hospitals operate in – and based on our checks, we would not be surprised to see such lawsuits filed over the next year or two.

Source: PACER.gov, Deutsche Bank estimates

Appendix 1

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Company	Ticker	Recent price*	Disclosure
Intuitive Surgical	ISRG.OQ	604.67 (USD) 18 Feb 2020	2, 8, 14, 15

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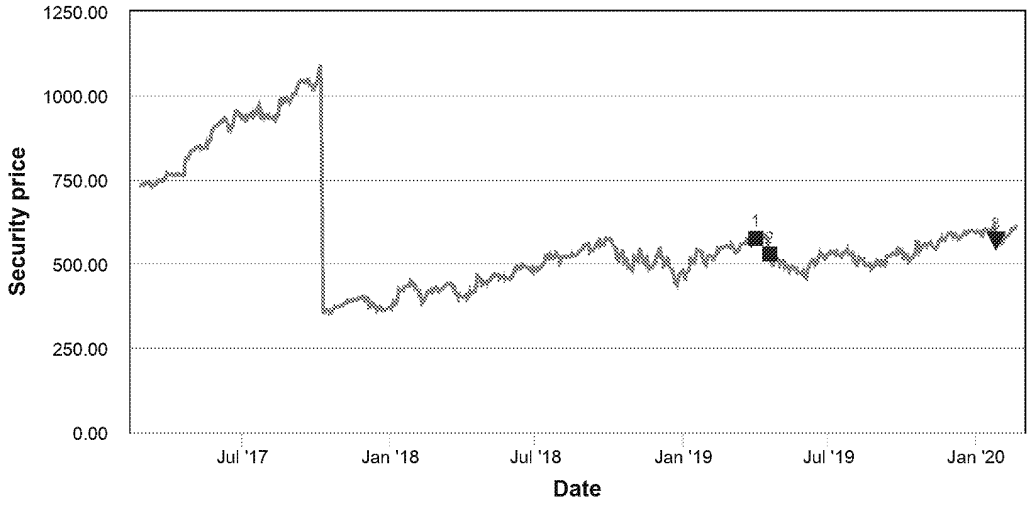
20 February 2020
Medical Supplies & Devices
Intuitive Surgical

Historical recommendations and target price: Intuitive Surgical (ISRG.OQ)

(as of 02/19/2020)



Current Recommendations
- Buy
- Hold
- Sell
- Not Rated
- Suspended Rating

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1. 04/02/2019 Buy, Target Price Change USD 630.00 Imron Zafar
2. 04/19/2019 Buy, Target Price Change USD 610.00 Imron Zafar
3. 01/27/2020 Downgraded to Hold, Target Price Change USD 595.00 Imron Zafar

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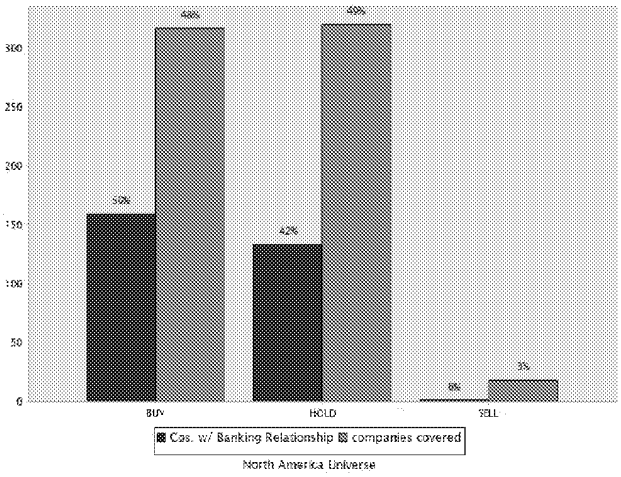

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